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10/663,010	09/15/2003	Tim Clarot	33205.0800	1757

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EXAMINER

ALSTRUM ACEVEDO, JAMES HENRY

ART UNIT	PAPER NUMBER
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1616

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10/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/663,010	Applicant(s) CLAROT ET AL.	
	Examiner James H. Alstrum-Acevedo	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 13-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-29 and 32-39 is/are rejected.
- 7) ☒ Claim(s) 30-31 and 40 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-11 and 13-40 are pending. Applicant previously cancelled claim 12. Applicants have amended claims 11, 24, 27, 30-32, 34, 37, and 40. Receipt and consideration of Applicants' claim amendments and remarks/arguments, submitted on August 1, 2007 are acknowledged.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 1, 2007 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 11, 13-32, and 34-35 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement **is withdrawn** per Applicants' amendments striking the previously introduced new matter.

Response to Arguments

Applicant's arguments, see page 9, filed August 1, 2007, with respect to the rejection of claims 11, 13-32, and 34-35 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new matter) have been fully considered and are persuasive. The rejection of claims 11, 13-32, and 34-35 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new matter) has been withdrawn.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

The rejection of claims 36-39 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn per Applicant's clarification of what is meant by a "system."

Response to Arguments

Applicant's arguments, see page 9, filed August 1, 2007, with respect to the rejection of claims 36-39 under 35 U.S.C. 112, second paragraph, as being indefinite have been fully considered and are persuasive. The rejection of claims 36-39 under 35 U.S.C. 112, second paragraph, as being indefinite has been withdrawn.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for

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patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claim 40 under 35 U.S.C. 102(e) as being anticipated by Haslwanter et al. (U.S. Patent No. 6,316,483) **is withdrawn** per Applicants' claim amendment requiring that the composition comprise 0.00001 to about 1.0 % w/w aloe barbadensis gel and 0.05% to about 5.0% w/w glycerin.

Response to Arguments

Applicant's arguments, see page 9, filed August 1, 2007, with respect to the rejection of claim 40 under 35 U.S.C. 102(e) as being anticipated by Haslwanter et al. (U.S. Patent No. 6,316,483) have been fully considered and are persuasive. The rejection of claim 40 under 35 U.S.C. 102(e) as being anticipated by Haslwanter et al. (U.S. Patent No. 6,316,483) has been withdrawn. It is noted that Applicants' traversal argument referred to "Haslwanter et al. (U.S. Patent No. 5,854,269)", however, this was in error, because the Haslwanter reference cited was actually U.S. Patent No. 6,316,483.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The rejections of (1) claims 1-11, 13-29, and 33-35 under 35 U.S.C. 103(a) as being unpatentable over Davidson (U.S. Patent No. 6,365,624) in view of Haslwanter et al. (U.S. Patent No. 5,854,269) **is maintained**, for the reasons of record as described in the office action mailed on December 1, 2005 and reiterated herein below.

Response to Arguments

Applicant's arguments filed August 1, 2007 have been fully considered but they are not persuasive. Applicants' have traversed the instant rejection by arguing that (1) there is no suggestion or motivation to modify the cited references or combine the references' teachings; and (2) menthol is incorporated in Applicants' claimed composition for a different purpose (i.e. as a decongestant) than that suggested by Haslwanter (i.e. to mask the characteristic odor of aromatic alcohols, such as benzyl alcohol).

The Examiner respectfully disagrees with Applicants' traversal arguments. Both Davidson and Haslwanter teach compositions comprising a combination of decongestants: (1)

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zinc gluconate and menthol (Davidson) or (2) oxymetazoline or pharmaceutically acceptable salt thereof and menthol (Haslwanter) for application to the nasal membrane (i.e. the prior art teaches nasal compositions). A skilled artisan would have been motivated to look to both Davidson and Haslwanter for guidance as to the required properties of a nasal decongestant composition (e.g. a viscosity greater than about 5,000 centipoise as taught by Davidson) as well as to decongestants that one could employ in such a composition (e.g. zinc gluconate (Davidson), menthol (Davidson & Haslwanter), and oxymetazoline (Haslwanter)). A skilled artisan would also have been motivated to combine the prior art references, because both utilize menthol, which is desirable, due to its ability to mask the odor of aromatic alcohols (Haslwanter, col. 1, lines 57-59). It is noted that the term "oxymetazoline or pharmaceutically acceptable salt thereof (e.g. oxymetazoline hydrochloride in Example 6)" reads on oxymetazoline hydrochloride; Haslwanter teaches oxymetazoline or pharmaceutically acceptable salt thereof in the range of about 0.01 % to about 0.1 % by weight/volume (w/v), which overlaps with the range claimed by Applicant. A person of ordinary skill in the art at the time of the instant invention would have had a reasonable expectation of success upon combination of the teachings of Haslwanter and Davidson, because both references teach nasal compositions comprising menthol. Regarding Applicants' argument (2), it is immaterial whether the reasons for combining the prior art teachings are the same as those motivating Applicants. Nonetheless, the combination is clearly suggested by the prior art, because (1) preservatives such as benzyl alcohol are explicitly suggested and thus would require odor masking and (2) the prior art also recognizes that menthol is a known decongestant (Davidson). Thus, the prior art provides ample suggestion and motivation to combine and modify the teachings of the cited references. The instant rejection is deemed to remain proper.

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The rejection of claims 30-31 under 35 U.S.C. 103(a) as being unpatentable over Davidson (U.S. Patent No. 6,365,624) in view of Haslwanter et al. (U.S. Patent No. 5,854,269), and further in view of Pier (U.S. Patent No. 6,245,735) **is withdrawn**, per Applicants' persuasive arguments regarding the combination of the teachings of Pier with the combined teachings of Davidson and Haslwanter.

Response to Arguments

Applicant's arguments, see pages 11-12, filed August 1, 2007, with respect to rejection of claims 30-31 under 35 U.S.C. 103(a) as being unpatentable over Davidson (U.S. Patent No. 6,365,624) in view of Haslwanter et al. (U.S. Patent No. 5,854,269), and further in view of Pier (U.S. Patent No. 6,245,735) have been fully considered and are persuasive. The rejection of claims 30-31 under 35 U.S.C. 103(a) as being unpatentable over Davidson (U.S. Patent No. 6,365,624) in view of Haslwanter et al. (U.S. Patent No. 5,854,269), and further in view of Pier (U.S. Patent No. 6,245,735) has been withdrawn.

The rejection of claims 36-39 under 35 U.S.C. 103(a) as being unpatentable over Davidson (U.S. Patent No. 6,365,624) in view of Haslwanter et al. (U.S. Patent No. 5,854,269), and further in view of Seidel et al. (US 2001/0053775) or MacRae et al. (US 2002/0046751) **is maintained** for the reasons of record and further articulated below.

Response to Arguments

Applicant's arguments filed August 1, 2007 have been fully considered but they are not persuasive. Applicants' have traversed the instant rejection by (1) restating their traversal arguments regarding the combination of Davidson (U.S. Patent No. 6,365,624) and Haslwanter et al. (U.S. Patent No. 5,854,269) and (2) stating that there is no motivation to combine the teachings of Seidel or MacRae with the teachings of Davidson and Haslwanter.

The Examiner respectfully disagrees with Applicants' traversal arguments. Regarding (1), these have been addressed above in the instant office action and are herein incorporated by reference. Regarding (2), Applicants' have provided no substantive arguments as to why an ordinary skilled artisan at the time of the instant invention would not have combined the teachings of Seidel or MacRae with the teachings of Davidson and Haslwanter. Thus, the instant rejection is deemed to remain proper.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejection of claim 29 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 10/664,839 (copending '839) **is maintained** for the reasons of record on page 12 of the office action mailed on December 1, 2005 and because Applicants have not provided any substantive arguments traversing the instant rejection. It is noted that copending '839 has issued as U.S. Patent No. 7,115,275, thus the instant rejection is no longer a provisional rejection.

The provisional rejection of claims 1 and 11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23-29 and 34 of copending Application No. 11/028,991 (copending '991) in view of Seifert (USPN 5,100,028; USPN '028) **is maintained** for the reasons of record on pages 12-13 of the office action mailed on December 1, 2005 and because Applicants have not provided any substantive arguments traversing the instant rejection.

Allowable Subject Matter

Claims 30-31 and 40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Conclusion

Claims 1-11 and 13-29, and 32-39 are rejected. Claims 30-31 and 40 are objected.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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